



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No. : **10/563737**
Applicant : **Bestmann**
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Title : **Sample Preparing Unit**
TC/A.U. : **1637**
Examiner : **Bertagna**
Docket No. : **5788**
Customer No. : **26936**

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ELECTION

Sir:

In response to the Restriction Requirement dated January 30, and subject to the traverse made below, Applicant hereby elects to prosecute the invention identified by the examiner as Group II, namely claims 37 - 56 and 66 - 72, without prejudice to the filing of a divisional application directed to the nonelected claims.

The requirement is traversed because, in our opinion, there is unity of invention between all the groups identified by the examiner. That is, they share a common inventive concept.

MPEP 1893.03(d) provides:

“The basic principle is that an application should relate to only one invention or, if there is more than one invention, that applicant would have a right to include in a single application only those inventions which are so linked as to form a single general inventive concept.

“A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art. For example, a corresponding technical feature is exemplified by a key defined by certain claimed structural characteristics which correspond to the claimed features of a lock to be used with the claimed key. Note also the examples contained in Chapter 10 of the International Search and Preliminary Examination Guidelines which can be obtained from WIPO's web site (www.wipo.int/pct/en/texts/gdlines.htm).

“A process is "specially adapted" for the manufacture of a product if the claimed process inherently produces the claimed product with the technical relationship being present between the claimed process and the claimed product. The expression "specially adapted" does not imply that the product could not also be manufactured by a different process.

“An apparatus or means is specifically designed for carrying out the process when the apparatus or means is suitable for carrying out the process with the technical relationship being present between the claimed apparatus or means and the claimed process. The expression specifically designed does not imply that the apparatus or means could not be used for carrying out another process, nor does it imply that the process could not be carried out using an alternative apparatus or means.”

In an accompanying amendment, we have combined claims 26 and 27 so that now the composition according to claim 26 is limited to a lyophilizate.

We submit that Chan (US 6355420, cited by the examiner) is not related to the concept of the present invention. In particular, Chan refers to compositions such as the ones claimed in claim 26 only in passing in column 93, in a very general way. There is no teaching in Chan about the composition being a lyophilizate, so claim 26 is novel over Chan.

As mentioned above, Chan is related to a completely different problem and only mentions in passing compositions for the PCR Technology. In contrast, the present invention aims at providing a safe, speedy and efficient procedure of preparing a reaction mixture for a PCR procedure. It was the surprising finding of the present invention that this problem is solved by providing a composition comprising all the essential ingredients for a PCR reaction in the form of a lyophilizate attached to a support (such as a membrane) in a device. The device is suitable for isolating the nucleotides to be detected by the PCR method from its original source by steps such as lysis and filtration. The purified nucleotide penetrates the support, preferably a membrane, to which the lyophilizate is attached, thereby becoming combined with the other components of the PCR reaction mixture. At the bottom of the device of the invention, the complete PCR reaction mixture is obtained. Thereby, the present invention overcomes the need of transferring the nucleotide from a first device where it is isolated from other components of the original source into a second device where it is combined with the other components of the PCR reaction mixture. By the solution of the present invention, apart from providing a very speedy and efficient procedure, also any risk of contamination of the PCR reaction mixture is avoided.

The subject matter of claim 26 (i.e. the composition in the form of a lyophilizate - Group I) has the same inventive concept as the device claims (Group II) or the method

claims (Groups III and IV). The common inventive concept which is required for the purposes of Rule 13.2 PCT (regarding unity of invention) is the provision of a composition in the form of a lyophilizate which when combined with a nucleotide source results in a complete PCR reaction mixture.

Respectfully submitted,



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